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August 31, 2011

VIA CM/ECF FILING AND HAND DELIVERY

The Honorable Leonard P. Stark United States District Court, District of Delaware J. Caleb Boggs Federal Building 844 N. King Street, Room 6100 Wilmington, DE 19801-3556

Re: The Procter & Gamble Company, et al. v. Teva Pharmaceuticals USA, Inc., C.A. No. 08-627-LPS (Consolidated)

Dear Judge Stark:

We represent Plaintiffs Hoffmann-La Roche Inc. ("Roche") and Warner Chilcott Company, LLC ("Warner Chilcott") in the above-identified consolidated actions. We write on behalf of Roche to address defendant Apotex's attempt to use Dr. Dennis Black, a long-time Roche consultant on matters relating to bisphosphonates and osteoporosis therapies, as an expert against Roche.

Roche respectfully seeks an order disqualifying Dr. Dennis Black from testifying as an expert on behalf of defendant Apotex, or, in the alternative, requiring Dr. Black to execute a Supplemental Protective Order Undertaking before providing expert consultation or testimony. Roche is similarly opposing Apotex's attempts to use Dr. Black as an expert in the related New Jersey actions, Hoffmann-La Roche Inc. v. Apotex Inc. and Apotex Corp., Civil Action No. 07-4417 (SRC)(MAS) (consolidated). See D.I. 334-336. Roche filed its motion and supporting brief on August 12, 2011. Apotex may file opposition papers on September 6, and Roche may file any reply papers on September 12, 2011. Id. at D.I. 337.

Factual Background

Since at least 1999, Dr. Black has been a consultant for Roche on many confidential matters relating to BONIVA®, and as recently as 2011 for Genentech (a member of the Roche Group and now also a co-plaintiff in the New Jersey actions). Dr. Black has signed numerous consulting and confidentiality agreements that are still in force today. In the course of his many discussions with Roche scientists and clinical trial coordinators, Dr. Black repeatedly

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received highly confidential Roche information related to issues in these actions – information that is not publicly available today.

Dr. Black consulted with Roche on the inventions that are the subject of the patents-in-suit, including monthly dosing of bisphosphonates to treat and prevent osteoporosis. Dr. Black was a member of advisory boards with which Roche consulted regarding the bisphosphonate market, and in that role received confidential competitive business and science information from Roche. Dr. Black was an expert witness for Roche in an action brought by Procter & Gamble (former plaintiff in these actions, now substituted by Warner Chilcott) relating to advertising for BONIVA® and ACTONEL®, in which Dr. Black provided expert opinions and received confidential information relating to BONIVA® clinical trials. As of 2011, Dr. Black serves as the Principal Investigator on a clinical study funded by Roche that examines the effects of monthly BONIVA® in combination with parathyroid hormone (PTH).

Roche's Efforts to Resolve this Issue

Roche first learned that Apotex intended to use Dr. Black as an expert in June 2011 when Apotex provided Roche with a Protective Order Undertaking signed by Dr. Black in March 2011. Roche made repeated efforts to persuade Apotex to withdraw Dr. Black as an expert, to no avail. In a June 2011 meet-and-confer, Apotex refused to provide any explanation for its delay in disclosing Dr. Black, and Apotex refused to comment on whether Apotex engaged in substantive discussions with Dr. Black regarding the subject matter of the instant litigations or in the related New Jersey actions involving BONIVA®. Apotex also refused to disclose whether Dr. Black had conveyed any Roche confidential information to Apotex's counsel — either before, or in the three months subsequent to, Dr. Black's March 2011 undertaking.

In an effort to protect Roche's interests while avoiding outright disqualification, Roche proposed that Apotex seek a Supplemental Undertaking from Dr. Black confirming that he will not consult with Defendants or provide testimony in this case relating to the subject matters of his consulting agreements with Roche. In response, Apotex informed Roche that it had consulted with Dr. Black and that he said he does not have any Roche confidential information and does not remember any Roche confidential information that has not since been made public.

Roche consulted with Dr. Charles Barr (a former Roche employee and current Genentech employee who worked with Dr. Black when he was a Roche consultant receiving confidential clinical trial data on BONIVA®) and others at Roche and Genentech regarding the scope of confidential information provided to Dr. Black, and concluded that Dr. Black is mistaken, and that Dr. Black has indeed received Roche confidential information that is not today public. Apotex refused to withdraw Dr. Black as an expert, Apotex did not identify any topic on which Dr. Black might be expected to testify, and Apotex would not obtain a Supplemental Undertaking from Dr. Black. This letter motion followed.

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The Court Should Protect Roche Against Dr. Black's Conflict of Interest

In determining whether Dr. Black should be disqualified, this Court must make two initial factual determinations as set forth in Cordy v. Sherwin Williams Co., 156 F.R.D. 575, 579 (D.N.J. 1994). First, it must have been objectively reasonable for Roche to believe that a confidential relationship existed with Dr. Black. Second, Roche must have actually disclosed confidential information to Dr. Black. Roche submits that both of these prongs are handily met here. Next, this Court should weigh policy considerations - namely, the Court's interest in preventing conflicts of interest and maintaining judicial integrity against fostering accessibility to experts with specialized knowledge and encouraging experts to pursue their vocations. See AstraZeneca Pharm. LP, et. al. v. Teva Pharm. USA, Inc., et. al., 2007 WL 4292384, at *1 (D.N.J. Dec. 4, 2007); see also U.S. ex rel. Cherry Hill Convalescent v. Healthcare Rehab Sys., 994 F. Supp. 244, 248-251 (D.N.J. 1997).

Apotex's attempt to use Dr. Black against Roche should be blocked by this Court. Apotex knew of Dr. Black's long history with Roche and his intimate knowledge of its confidential thought processes and plans relating to BONIVA® when it induced him to sign up as Apotex's expert in this action; the nature of Dr. Black's relationship with Roche was detailed to Apotex over the past several months. This Court should not permit Dr. Black to use, even unintentionally, the Roche confidential information permeating his knowledge of bisphosphonates against Roche in this action.

Apotex will not suffer any prejudice if it cannot rely on Dr. Black. Apotex has relied on its expert Dr. Yates in the present actions, and has retained several other experts in the related New Jersey actions — experts who, unlike Dr. Black, have already submitted expert reports and who are not under long-standing obligations of confidentiality to Roche.

Conclusion

To preserve the fairness and integrity of these proceedings, this Court should exercise its inherent power to disqualify experts and bar Dr. Black from testifying as an expert against Plaintiffs and on behalf of Apotex and Defendants in the present litigations. In the alternative, the Court should require Dr. Black to execute a Supplemental Undertaking confirming (1) he has reviewed his previous confidentiality and consulting agreements with Roche and Genentech, (2) he will abide by them, and (3) he will not consult with Apotex or provide testimony in this case relating to the subject matters of the agreements.

Respectfully submitted,

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cc: All Counsel of Record (via email)